

Telehealth: Applications From a Legal and Regulatory Perspective

Rita M. Marcoux, RPh, MBA; and F. Randy Vogenberg, RPh, PhD



Keywords: telehealth, telemedicine, mHealth, e-Health, Centers for Medicare and Medicaid Services, Patient Protection and Affordable Care Act, health care delivery, health care reimbursement

Introduction

Telehealth—the remote delivery of health care to a patient through technology—is becoming mainstream in the United States as economic and resource constraints continue to impact the current method of health care delivery and reimbursement models move toward performance-based outcomes and metrics. Over 50% of hospital systems utilized some form of telehealth in 2013,¹ and the technology has reached the retail market as well, with national companies such as Walgreens launching their own telehealth programs and applications (apps) directly to consumers.² It has been predicted that the telemedicine market will soar past \$30 billion by 2020.³

Defining Telehealth

The term telehealth is used interchangeably with telemedicine by some

organizations. The term telemedicine is generally associated with the delivery of traditional clinical diagnosis and monitoring by technology and is a subset of the services encompassed by the term telehealth. Telehealth's broader definition encompasses clinical health care as well as a wide range of other services, including educating patients and providers, and promoting disease awareness and wellness. Telehealth uses innovative technologies, such as kiosks, website monitoring applications, mobile phone applications, wearable devices, and videoconferencing, to remotely connect health care providers to patients.

The Health Resources and Services Administration defines telehealth as “the use of electronic information and telecommunications technologies to support long-distance clinical health care, patient and professional health-related education, public health, and health administration.”⁴

The Federation of State Medical Boards (FSMB) defines telehealth as “the practice of medicine using electronic communications, information technology, or other means between a licensee in one location and a patient in another location with or without an intervening health care provider.” The FSMB definition was included in its model policy to assist state medical boards in managing this emerging area of practice that crosses multiple states and domains, as well as to ensure patient care and safety.⁵

The list of services included in telehealth continues to expand as providers seek to reach more patients, and as systems manage coverage gaps in services or service areas and support the transition from acute or emergency care to a patient-centric preventive approach.

Approaches to Telehealth

Traditionally, telehealth delivery is segmented into four modalities: real-time, store-and-forward, remote patient monitoring (RPM), and mobile health (mHealth).

Real-time (synchronous) telehealth is used to consult with, diagnose, and

treat patients. The key to this modality is that the patient and provider see each other and are actively engaged in the interaction. This modality is generally what is referred to when using the term telemedicine and is the service most commonly reimbursed by health care plans.

The store-and-forward (asynchronous) modality is used to send electronic medical communications, often to a specialist, to assist in evaluating a patient's case or to deliver a service outside of a typical face-to-face encounter.

The RPM modality collects patient information electronically and transmits it to a provider at another location to allow tracking and monitoring of that patient. Common RPMs include glucose and blood pressure monitoring. This type of monitoring is critical as the industry moves toward pay-for-performance reimbursement methods. In addition, RPMs may assist hospitals in monitoring newly released patients in an effort to prevent readmissions from complications after discharge. Chronic conditions are well serviced by RPM as well. For example, the Veterans Administration (VA)—one of the largest users of RPM services—reported that its Care Coordination/Home Telehealth program monitored and cared for more than 70,000 veterans with chronic diseases in 2012, and that patient satisfaction levels were greater than 85%. The VA also reported more than \$9,000 in savings per patient due to the reduction in the number of hospitalizations.⁶

The newest modality is mHealth, which includes online services and mobile phone apps marketed directly to consumers. The global market for wearable devices to help consumers track their health and wellness is expected to reach \$49 billion by 2020.⁷

Addressing Primary Care Challenges

The expansion of telehealth is being driven by a number of challenges and opportunities in the current health care

Rita M. Marcoux is Clinical Associate Professor of Managed Care Pharmacy and Director of Pharmacy Outreach Programs, working with older Americans, minority populations, and the Department of Corrections, at the University of Rhode Island College of Pharmacy in Kingston, Rhode Island. F. Randy Vogenberg, PhD, the editor of this column, is a pharmacist with a doctorate in health care management. He is a member of P&T's editorial board and a Fellow of the American Society of Health-System Pharmacists. He has lectured on health care policy and law and has presented continuing education seminars on risk management in the health professions throughout his career. Dr. Vogenberg is Principal at the Institute for Integrated Healthcare and National Institute of Collaborative Healthcare in Greenville, South Carolina, and Adjunct Professor of Pharmacy Administration at the University of Rhode Island College of Pharmacy. His email address is randy@nich-online.com.

delivery system. Access to primary care in rural and underserved areas is a significant driver for the Centers for Medicare and Medicaid Services' (CMS) programs. While CMS's Medicare program is experiencing significant growth as "baby-boomers" transition to Medicare, the availability of primary care providers is limited. In addition, health plans and consumers are behind an intended shift of the management of chronic diseases from the long-term-care facility to the home setting. This movement necessitates that providers have the information they need to manage and prevent emergency room visits and hospitalizations. Technology, such as monitoring devices, collects patients' data, allowing providers to quickly address patient issues before they become acute. The Federal Communications Commission (FCC) has estimated that, over a 25-year period, RPM could save an estimated \$197 billion in just three areas: pulmonary disease, diabetes, and cardiac disease.⁸

The expansion of state Medicaid programs by the Patient Protection and Affordable Care Act (PPACA) also has increased the need for primary care providers, most notably in rural and underserved areas. This immediate need to provide health care services to increasing numbers of beneficiaries has pushed state Medicaid programs to seek innovative solutions to address the lack of availability of traditional face-to-face provider interactions. The federal government's emphasis is to use technology to provide services that increase efficiency, are economical to the state, and improve quality of care for patients. Lastly, the changing health care paradigm, in which consumers bear an increasing amount of the health care cost and providers are evaluated and paid by performance measure, mandates collaboration between providers and their patients if goals and outcomes are to be reached.

Reimbursement

Seeking reimbursement is an important legislative and regulatory initiative for telehealth software and services providers. Twenty-three states have telehealth parity laws for private insurance; however, the language of these laws is key to what is covered. If the law is written to mimic what is available

in person, a gap may appear in the areas of RPM or online app-based programs available through mHealth. To address these gaps, some states have submitted revisions or additional bills to expand coverage to services not previously covered in the original bills.⁹

Similarly, federal programs vary in their coverage of telehealth. For example, Medicare covers a range of services from telecommunications to patient access to care across a distance, but caveats such as coverage based on rural versus non-rural service areas exist. Several interested organizations addressed a letter to Health and Human Services (HHS) Secretary Sylvia Mathews Burwell in 2014 highlighting that Medicare coverage limitation criteria excluded 80% of Medicare beneficiaries who live in nonrural areas.¹⁰ In their assessment of Medicare reimbursement for telehealth in 2014, the Robert J. Waters Center for Telehealth and e-Health Law found that the agency's expenditures totaled \$13.9 million.¹¹ The restrictions on coverage established by Medicare limit expansion of telehealth services by providers. However, Medicare Advantage programs do not have the same coverage limitation. Humana and Anthem also have included telehealth services in some of their Advantage programs.

The Medicaid program recognizes the benefit of utilizing telemedicine as a means to meet the federal mandate to promote efficiency, economy, and quality of care to its beneficiaries. The Medicaid program language defines telemedicine as real-time, two-way communication between a patient and a provider at a distant site. The telemedicine definition for Medicaid is modeled on Medicare's definition. Under Medicaid, the store-and-forward modality would not be considered telemedicine but is allowed as a means to deliver services. Telehealth is not considered part of Medicaid's definition, but it is often reimbursed by states under the umbrella of telemedicine services.¹² Forty-eight state Medicaid programs provide some type of coverage for telemedicine. Of the 48 programs, 24 states do not specify a patient setting for payment, while 25 states recognize the home as an originating site and 16 recognize a school as an originating site. Fifteen states and the District of Columbia do not specify the type of

provider allowed for reimbursement. State rules governing the coverage of specialty providers vary tremendously.⁹

Some employers include telehealth as part of their benefit packages. In a 2014 survey of 1,000 employers by Towers Watson, an estimated 37% of employers indicated that telemedicine options were added to their employee plan in 2015, and 34% indicated they had plans to add the option in 2016 or 2017.¹³ Adding telehealth services to benefit packages is an effort to minimize the use of high-cost emergency room services. A second factor motivating employers is the potential reduction or elimination of time off required by an employee to physically go to a physician's office.

Even insurers, such as Blue Cross Blue Shield (BCBS) of Alabama, that were initially resistant to reimbursing for telehealth services have modified their stance. In December 2015, BCBS of Alabama began reimbursing providers for five telehealth services: cardiologic conditions, behavioral health, dermatological conditions, infectious disease, and neurological diseases, including stroke.^{14,15} Reimbursement models vary among companies and include a fee per-member/per-month, fee-for-service, or a mixed model of the two.

Regulations

In 2012, Congress passed the Food and Drug Administration Safety and Innovation Act, a section of which tasked the Food and Drug Administration (FDA), in consultation with the FCC and the Office of the National Coordinator for Health Information Technology (ONC), with developing "strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health information technology, including mobile medical apps, that promotes innovation, protects patient safety, and avoids regulatory duplication."¹⁶ In April 2014, the FDA, the FCC, and the ONC entered into a memorandum of understanding in which the agencies agreed to collaborate within the areas of their respective scopes of authority on existing technology and on emerging innovations in mHealth and to regulate their usage.^{17,18}

While the FDA/FCC/ONC collaboration works to promote innovation and protect patient safety, the Federal Trade Commission (FTC) protects

consumers from unfair or deceptive acts or practices and from false or misleading claims. In telehealth, the FTC's focus is on the effectiveness of mHealth devices and apps. A significant emerging concern is the security of patient health information collected through mHealth apps by entities not covered by the Health Insurance Portability and Accountability Act. The FTC has jurisdiction over non-covered entities and is therefore authorized to address data breaches associated with mHealth apps.¹⁷

For telehealth practitioners, this field of practice poses a number of logistical challenges. Although there has been a considerable amount of state policy activity in an effort to increase utilization and reimbursement for telehealth, health care providers continue to encounter conflicting and confusing policies in terms of requirements for insurance claims, practice standards, and licensure.¹⁹ Individual practitioners are required to be licensed by the state in which they practice as well as in the state in which the patient resides, which may be a hindrance to utilization and accessibility. The portability of licensure across state lines remains a contentious issue, and many believe it inhibits the growth of telehealth services.¹⁹

A number of states have started to review their regulations of telehealth services and the definition of the patient-provider relationship. The FSMB model policy on telehealth recommended that the same standard of care be applied in in-person and remote consultations. The policy does not state that a pre-existing physician-patient relationship is required.⁵ The American Medical Association's statement on telehealth, however, indicates that a "face-to-face relationship" between a physician and a patient should exist prior to a telemedicine encounter.²⁰

Conflicting state regulations for practitioners and practice must be reconciled for telehealth to reach its potential.

Outlook on Law and Regulation

On a national level, the federal government is investigating the expansion of telehealth to address access as well as quality and cost of care. Senators John Thune (R-South Dakota) and Bill Nelson (D-Florida) requested a literature review of the impact of telehealth on health care to date. In June 2016, the Agency

for Healthcare Research and Quality (AHRQ) delivered that report, which supported the effectiveness of telehealth for RPM, communication, and counseling for patients with several chronic conditions, and for psychotherapy as a part of behavioral health. The benefits for patients with chronic conditions, such as cardiovascular and respiratory disease, included improvements in mortality and quality of life, and reductions in hospital admissions. The AHRQ identified a number of areas, such as maternal health, child health, and triage for urgent care, that require more primary literature and review to determine the value of telehealth.²¹

In addition to these findings, several bills have been introduced in Congress to improve the scope of telehealth in Medicare. In December 2015, the bipartisan Telehealth Innovation and Improvement Act was introduced first in the House of Representatives by Representatives Diane Black (R-Tennessee) and Scott H. Peters (D-California)²² and then in the Senate by Senators Gary Peters (D-Michigan) and Cory Gardner (R-Colorado).²³ The bills are identical and address the lack of Medicare coverage for telehealth services, which the senators believe sets a poor industry standard, discourages innovation, and restricts access to specialized services.²⁴ The bills require HHS's Center for Medicare and Medicaid Innovation (CMMI) to allow eligible hospitals to test telehealth services. The CMMI must also review and independently evaluate telehealth models for cost, effectiveness, and improvement in quality of care without increasing the cost of delivery. If those criteria are met, then the model will be covered through the greater Medicare program. The bills were referred to various House and Senate committees for consideration.^{22,23}

In February 2016, Senator Brian Schatz (D-Hawaii) and Representative Black introduced the Creating Opportunities Now for Necessary and Effective Care Technologies (CONNECT) for Health Act in the Senate and the House, respectively. The identical bills, designed to "promote cost savings and quality care under the Medicare program through the use of telehealth and remote patient monitoring services,"^{25,26} address the use of those services and how they would be covered by Medicare's merit-based

incentive payment system and alternative payment models. The bill would establish a demonstration waiver program for eligible providers with the goal of alleviating current Medicare fee-for-service limitations on telehealth to expand coverage for patients.²⁷ The bills were referred to various House and Senate committees for consideration.

Conclusion

Telehealth continues to grow in scope, along with improved quality assurance of its services. Much like the standardization of information technology, telehealth remains an evolving area for effective delivery of care with standardized information sharing.

Licensing for telehealth remains a multilayered effort with state-by-state inconsistencies that have restricted the wide application of telemedicine or telepharmacy. Standardized legal and/or regulatory frameworks remain elusive. Reimbursement typically follows a clear legal framework using strategies to support appropriate use of telehealth in delivering care. The lack of clarity in the law creates inconsistent reimbursement by payers to care providers. Ultimately, a clear legal framework is required if reimbursement dilemmas are to be solved.

Information technology and system interconnectivity for record sharing across providers—physician, pharmacy, laboratories, and hospital systems—are necessary to ensure appropriate care. Technology development along with appropriate utilization of telehealth platforms continues at a rapid pace, driven in part by the ongoing implementation of the PPACA.

The increased chronic care burden in all cross-sections of the U.S. continues to pressure the health care delivery system to use innovative approaches and technology, such as telehealth, to provide cost-efficient care. Because remote pharmaceutical management or telepharmacy applications lag behind other telehealth services, the value of these services needs to be demonstrated through economic and clinical assessments in real-world settings. The cost-efficiency of telehealth, along with its ability to deliver easier access to timely medical or pharmaceutical care, proposes a unique value proposition. Determining that value remains to be done.

REFERENCES

1. *Trendwatch: The Promise of Telehealth for Hospitals, Health Systems, and Their Communities*. Washington, D.C.: American Hospital Association; 2015. Available at: www.aha.org/research/reports/tw/15jan-tw-telehealth.pdf. Accessed January 27, 2016.
2. Walgreens. Walgreens announces new digital health initiatives; expands access to enhanced MDLIVE live doctor consultation offering to 20 additional states, now totaling 25. November 10, 2015. Available at: <http://news.walgreens.com/press-releases/general-news/walgreens-announces-new-digital-health-initiatives-expands-access-to-enhanced-mdlive-live-doctor-consultation-offering-to-20-additional-states-now-totaling-25.htm>. Accessed February 3, 2016.
3. *Global Telemedicine Market—Growth Trend and Forecast (2012-2015)*. Hyderabad, India: Mordor Intelligence; 2015.
4. Health Resources and Services Administration. What is telehealth? Available at: www.hrsa.gov/healthit/toolbox/RuralHealthIT-toolbox/Telehealth/whatistelehealth.html. Accessed January 4, 2016.
5. State Medical Boards' Appropriate Regulation of Telemedicine (SMART) Workgroup. Model policy for the appropriate use of telemedicine technologies in the practice of medicine. Federation of State Medical Boards. April 2014. Available at: www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/FSMB_Telemedicine_Policy.pdf. Accessed January 22, 2016.
6. Broderick A, Lindeman D. *Scaling Telehealth Programs: Lessons from Early Adopters*. New York, New York: The Commonwealth Fund; 2013.
7. Slabodkin G. Global mHealth market projected to reach \$49 billion by 2020. Health Data Management. March 7, 2014. Available at: www.healthdatamanagement.com/news/global-mhealth-market-projected-to-reach-49-billion-by-2020. Accessed January 4, 2016.
8. Gottheimer J, Uppaluru M. FCC chairman challenges the private sector to accelerate the next generation of wireless health. Federal Communications Commission. June 15, 2012. Available at: www.fcc.gov/news-events/blog/2012/06/15/fcc-chairman-challenges-private-sector-accelerate-next-generation. Accessed January 27, 2016.
9. Thomas L, Capistrant G. *State Telemedicine Gaps Analysis: Coverage and Reimbursement*. Washington, D.C.: American Telemedicine Association; 2015. Available at: www.americantelemed.org/docs/default-source/policy/50-state-telemedicine-gaps-analysis-coverage-and-reimbursement.pdf. Accessed July 28, 2016.
10. Terry K. Burwell asked to lift barriers on telehealth reimbursement. June 11, 2014. Medscape. Available at: www.medscape.com/viewarticle/826579. Accessed January 4, 2016.
11. Robert J. Waters Center for Telehealth and e-Health Law. CMS reimburses nearly \$14 million for telemedicine in 2014. May 8, 2015. Available at: <http://ctel.org/2015/05/cms-medicare-reimburses-nearly-14-million-for-telemedicine-in-2014>. Accessed January 25, 2016.
12. Centers for Medicare and Medicaid Services. Telemedicine. Available at: www.medicare.gov/Medicare-CHIP-Program-Information/By-Topics/Delivery-Systems/Telemedicine.html. Accessed January 20, 2016.
13. Towers Watson. Current telemedicine technology could mean big savings. August 11, 2014. Available at: www.towerswatson.com/en-US/Press/2014/08/current-telemedicine-technology-could-mean-big-savings. Accessed January 26, 2016.
14. Herman B. Virtual reality: more insurers are embracing telehealth. *Modern Healthcare*. February 20, 2016. Available at: www.modernhealthcare.com/article/20160220/MAGAZINE/302209980. Accessed February 22, 2016.
15. Blue Cross Blue Shield Association. Blue Cross and Blue Shield of Alabama providing greater access to quality healthcare for Alabamians through telemedicine services. November 30, 2015. Available at: www.bcbs.com/healthcare-news/plans/BCBS-AL-telemedicine-services.html. Accessed July 25, 2016.
16. Food and Drug Administration Safety and Innovation Act. 21 USC § 618 (2012).
17. Center for Connected Health Policy. mHealth laws and regulations. Available at: <http://cchpca.org/mhealth-laws-and-regulations>. Accessed January 12, 2016.
18. Food and Drug Administration. MOU 2225-14-0002. April 28, 2014. Available at: www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstanding-MOUs/DomesticMOUs/ucm395150.htm. Accessed July 25, 2016.
19. Thomas L, Capistrant G. *State Telemedicine Gaps Analysis: Physician Practice Standards and Licensure*. Washington, D.C.: American Telemedicine Association; 2016. Available at: www.americantelemed.org/docs/default-source/policy/2016_50-state-telehealth-gaps-analysis-md-physician-practices-licensure.pdf?sfvrsn=2. Accessed July 26, 2016.
20. American Medical Association. AMA adopts telemedicine policy to improve access to care for patients. June 11, 2014. Available at: www.ama-assn.org/ama/pub/news/news/2014/2014-06-11-policy-coverage-reimbursement-for-telemedicine.page. Accessed January 22, 2016.
21. Totten AM, Womack DM, Eden KB, et al. *Telehealth: Mapping the Evidence for Patient Outcomes From Systematic Reviews*. Technical Brief No. 26. (Prepared by the Pacific Northwest Evidence-Based Practice Center under contract No. 290-2015-00009-I.) AHRQ Publication No.16-EHC034-EF. Rockville, Maryland: Agency for Healthcare Research and Quality; June 2016. Available at: www.effectivehealthcare.ahrq.gov/reports/final.cfm. Accessed July 26, 2016.
22. Black D, Peters SH. H.R. 4155—Telehealth Innovation and Improvement Act of 2015. December 2, 2015. Available at: www.congress.gov/bill/114th-congress/house-bill/4155/text. Accessed July 27, 2016.
23. Gardner C, Peters GC. S. 2343—Telehealth Innovation and Improvement Act of 2015. December 2, 2015. Available at: www.congress.gov/bill/114th-congress/senate-bill/2343/text. Accessed July 27, 2016.
24. Office of Gary Peters. Peters, Gardner introduce bill to expand access to telehealth services. December 2, 2015. Available at: www.peters.senate.gov/newsroom/press-releases/peters-gardner-introduce-bill-to-expand-access-to-telehealth-services. Accessed July 26, 2016.
25. Schatz B, Wicker RF, Cochran T, et al. S. 2484—Creating Opportunities Now for Necessary and Effective Care Technologies (CONNECT) for Health Act. February 2, 2016. Available at: www.congress.gov/bill/114th-congress/senate-bill/2484/text. Accessed July 26, 2016.
26. Black D, Welch P, Harper G, et al. H.R. 4442—Creating Opportunities Now for Necessary and Effective Care Technologies (CONNECT) for Health Act. February 3, 2016. Available at: www.congress.gov/bill/114th-congress/house-bill/4442/text. Accessed July 26, 2016.
27. Public Health Institute Center for Connected Health Policy. Bill Analysis: CONNECT for Health Act. February 2016. Available at: <http://cchpca.org/sites/default/files/resources/Schatz%20Factsheet%203-9-16.pdf>. Accessed July 26, 2016. ■

Corrections

- An article in the July issue of *P&T* on the Centers for Medicare and Medicaid Services (CMS) Medication Therapy Management pilot program said that participants would have to wait five years to obtain a premium subsidy. In fact, the CMS will pay those subsidies two years after a prescription drug plan earns them.
- The "Pipeline Plus" feature in the August issue of *P&T* incorrectly stated that the Food and Drug Administration approved lenvatinib (Lenvima, Eisai), in combination with everolimus, for second-line treatment of patients with advanced renal-cell carcinoma after prior antiangiogenic therapy in January 2016. The actual approval date was May 13, 2016.